REMARKS

I. Introductory Comments

In the Office Action under reply, the Examiner has rejected the claims as follows: under 35 U.S.C. §102(b) as allegedly being anticipated by Harris et al. (U.S. Patent Application Publication No. 2001/0011115) (claims 35, 47 and 52); under 35 U.S.C. §102(e) as allegedly being anticipated by Harris et al. (U.S. Patent No. 6,348,558) (claims 35, 47 and 52); under 35 U.S.C. §102(e) as allegedly being anticipated by Bentley et al. (U.S. Patent No. 6,448,369); under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 7 and 8 of U.S. Patent No. 6,348,558 (claims 35, 47 and 52); and under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 7 and 8 of U.S. Patent No. 6,448,369 (claims 35, 47, and 52).

II. Status of and Amendments to the Claims

Claims 35-53, 170-182, 184, 187 and 188 were previously pending. Claim 35 has been amended. No claims have been added or cancelled.

The Examiner indicated that claims 37, 40, 46, 50, 51, 170-182, 184 and 187-188 were withdrawn from further consideration. The Examiner has also indicated, however, that no relevant art was found for non-elected species in claims 36, 37 and 53. Moreover, Applicants believe that the subject matter of generic claim 35 will be allowable upon consideration of one or more arguments made herein. Consequently, Applicants have *not* indicated that claims 37, 40, 46, 50 and 51 are "withdrawn" as each of these claims was searched by the Examiner and/or depend on a generic claim that is believed to be allowable. Applicants have, however, indicated claims 170-182, 184 and 187-188 as being "withdrawn."

Thus, claims 35-53 are believed to be under consideration. If the Examiner's understanding is different, the Examiner is respectfully asked to clarify the status of the claims in the next communication.

Support for the changes to the claims is identified below. Additional support other than that identified below may exist in the originally filed application for one or more changes to the claims.

Claim 35 has been amended to recite "a carbon atom is attached on each side of the functional group." Support for the change can be found on page in the paragraph bridging pages 21 and 22 of the originally filed specification. The remaining changes are formal in nature and intended to improve the readability of the claim.

As support for the changes is found in the application as filed, no new matter is introduced by the entry of the above-identified changes. The changes to the claims are made for clarification purposes only should not be interpreted as acquiescence in any claim rejection.

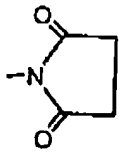
III. The Rejection Under 35 U.S.C. §102(b)

The Examiner has rejected claims 35, 47 and 52 under 35 U.S.C. §102(b) as allegedly being anticipated by Harris et al. (U.S. Patent Application Publication No. 2001/001115). Ostensibly, the Examiner has taken the position that each and every element of the rejected claims is disclosed by Harris et al.

The rejection is respectfully traversed in view of the following remarks.

The standard for anticipation is rigorous requiring that every element of the claimed invention be disclosed by a single prior art reference. *See Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 (Fed.Cir.1992); *Scripps*, 927 F.2d at 1576-77; *Lindemann Maschinenfabrik GMBH, v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458 (Fed.Cir.1984).

The Examiner cites Harris et al. (U.S. Patent Application Publication No. 2001/0011115) as teaching PEG derivatives with proximal reactive groups which include N-succinimidyl. As shown in paragraph [0013] of Harris et al., the chemical structure of N-succinimidyl is as follows,

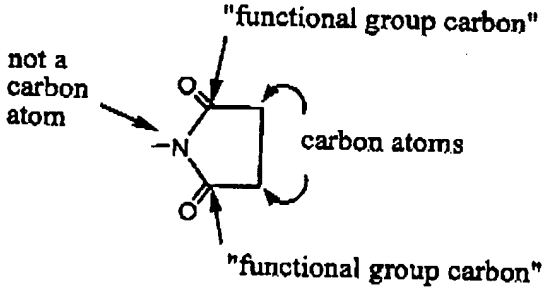


"N-succinimidyl structure."

The Examiner alleges that "N-succinimidyl ... would satisfy a functional group (ketone) attached to a cyclic ring (pyrrolidine)."

In contrast, Applicants defined the relevant functional groups (e.g., ketone) as including a "functional group carbon," wherein "a carbon atom must be attached on each side of the functional group carbon in order to provide the named functional group." Thus, with respect to a

ketone, the specification defines a ketone as having a  structure (wherein the asterisk designates the "functional group carbon" (i.e., a carbon having, among other things, a carbon on each side of the functional group carbon). In contrast, the N-succinimidyl structure relied upon by the Examiner has no carbon atom attached on each side of the "functional group carbon."



Consequently, the N-succinimidyl-based PEG derivatives relied upon by the Examiner do not include a "functional group" as that group is defined by Applicants.

Moreover, and only in an effort to advance the prosecution of the present application, Applicants have amended the independent claims to recite that a carbon atom is attached on each side of the functional group.

Thus, it is clear that Harris et al. (U.S. Patent Application Publication No. 2001/0011115) does not teach each and every element of the claimed subject matter. As a consequence, reconsideration and removal of the rejection under 35 U.S.C. 102(a) for at least the reason provided above are respectfully requested.

IV. The First Rejection Under 35 U.S.C. §102(e)

The Examiner has rejected claims 35, 47 and 52 under 35 U.S.C. §102(e) as allegedly being anticipated by Harris et al. (U.S. Patent No. 6,348,558)

The rejection is respectfully traversed in view of the following remarks.

The standard for anticipation is provided in Section III, *supra*.

Like Harris et al. (U.S. Patent Application Publication No. 2001/0011115) discussed in Section III, Harris et al. (U.S. Patent No. 6,348,558) is cited by the Examiner as teaching "PEG derivatives with proximal reactive groups which includes N-succinimidyl." See page 3 of the instant Office Action. Thus, for the same reason provided above in Section III with respect to

Harris et al. (U.S. Patent Application Publication No. 2001/0011115), the claimed subject fails to be anticipated by the disclosure of Harris et al. (U.S. Patent No. 6,348,558).

Consequently, reconsideration and removal of the rejection under 35 U.S.C. 102(a) for at least this reason are respectfully requested.

V. The Second Rejection Under 35 U.S.C. §102(e)

The Examiner has rejected claims 35, 47 and 52 under 35 U.S.C. §102(e) as allegedly being anticipated by Bentley et al. (U.S. Patent No. 6,448,369)

The rejection is respectfully traversed in view of the following remarks.

The standard for anticipation is provided in Section III, *supra*.

Like Harris et al. (U.S. Patent Application Publication No. 2001/0011115) discussed in Section III, Bentley et al. is cited by the Examiner as teaching "PEG derivatives with proximal reactive groups which includes N-succinimidyl." See page 3 of the instant Office Action. Thus, for the same reason provided above in Section III with respect to Harris et al. (U.S. Patent Application Publication No. 2001/0011115), the claimed subject fails to be anticipated by the disclosure of Bentley et al.

Consequently, reconsideration and removal of the rejection under 35 U.S.C. 102(a) for at least this reason are respectfully requested.

VI. The First Obviousness-Type Double Patenting Rejection

Claims 35, 47 and 52 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 7 and 8 of U.S. Patent No. 6,348,558. On page 4 of the instant Office Action, the Examiner alleged that "[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because both claim PEG derivatives with proximal reactive groups that may contain a cyclic structure with a functional group."

The rejection is traversed in view of the following comments.

The analysis employed in an obviousness-type double patenting determination parallels the guidelines for a 35 U.S.C. §103(a) rejection. See Section 804 (II)(B)(1) of the Manual of Patent Examining Procedure. Thus, to establish a *prima facie* case of obviousness under 35

U.S.C. §103(a) rejection, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Here, the Examiner has taken the position that claims 7 and 8 of U.S. Patent No. 6,348,558 claim derivatives with proximal reactive groups that may contain a cyclic structure with a functional group.

As pointed out above in Section III, however, a carbon atom is attached on each side of the functional group, wherein the functional group is selected from the group consisting of ketone, ketone hydrate, thione, monothiohydrate, dithiohydrate, hemiketal, monothiohemiketal, dithiohemiketal, ketal, and dithioketal. There is no teaching or suggestion of this element within the subject matter encompassed by claims 7 and 8 of U.S. Patent No. 6,348,558.

Moreover, there is no suggestion or motivation within the subject matter of claims 7 and 8 of U.S. Patent No. 6,348,558 to use the specific functional groups encompassed by Applicants' presently pending claims or to switch those groups recited in claims 7 and 8 of U.S. Patent No. 6,348,558 for those encompassed by Applicants' presently pending claims.

Thus, as claims 7 and 8 of U.S. Patent No. 6,348,558 fail to (a) teach or suggest all the claim features, and (b) suggest or motivate one of ordinary skill in the art to make the requisite modifications to arrive at Applicants' presently pending claims, the first and third elements for establishing *prima facie* obviousness are not satisfied. Consequently, since the obviousness-type double patenting determination parallels the guidelines of an obvious rejection and *prima facie* obviousness has not been satisfied, reconsideration and removal of the double patenting rejection for at least these reasons are respectfully requested.

VII. The Second Obviousness-Type Double Patenting Rejection

Claims 35, 47 and 52 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 7 and 8 of U.S. Patent No.

6,448,369. On page 5 of the instant Office Action, the Examiner alleged that "[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because both claim PEG derivatives with proximal reactive groups that may contain a cyclic structure with a functional group."

The rejection is traversed in view of the following comments.

The standard establishing an obviousness-type double patenting rejection was provided in Section VI, *supra*.

Here, the Examiner has taken the position that claims 7 and 8 of U.S. Patent No. 6,448,369 claim derivatives with proximal reactive groups that may contain a cyclic structure with a functional group.

As pointed out above in Section III, however, a carbon atom is attached on each side of the functional group, wherein the functional group is selected from the group consisting of ketone, ketone hydrate, thione, monothiohydrate, dithiohydrate, hemiketal, monothiohemiketal, dithiohemiketal, ketal, and dithioketal. There is no teaching or suggestion of this element within the subject matter encompassed by claims 7 and 8 of U.S. Patent No. 6,448,369.

Moreover, there is no suggestion or motivation within the subject matter of claims 7 and 8 of U.S. Patent No. 6,448,369 to use the specific functional groups encompassed by Applicants' presently pending claims or to switch those groups recited in claims 7 and 8 of U.S. Patent No. 6,448,369 for those encompassed by Applicants' presently pending claims.

Thus, as claims 7 and 8 of U.S. Patent No. 6,448,369 fail to (a) teach or suggest all the claim features, and (b) suggest or motivate one of ordinary skill in the art to make the requisite modifications to arrive at Applicants' presently pending claims, the first and third elements for establishing *prima facie* obviousness are not satisfied. Consequently, since the obviousness-type double patenting determination parallels the guidelines of an obvious rejection and *prima facie* obviousness has not been satisfied, reconsideration and removal of the double patenting rejection for at least these reasons are respectfully requested.

VIII. Conclusion

In view of the foregoing, Applicants submit that the pending claims satisfy the requirements of patentability and are therefore in condition for allowance. Reconsideration and withdrawal of all

objections and rejections are respectfully requested and a prompt mailing of a Notice of Allowance is earnestly solicited.

If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 620-5506.

Respectfully submitted,

Date: September 28, 2006

By: Mark A. Wilson

Mark A. Wilson
Registration No. 43,275

Nektar Therapeutics
150 Industrial Road
San Carlos, CA 94070
(650) 631-3100 (Telephone)
(650) 631-3125 (Facsimile)